with a TASC D classification who underwent endovascular stenting for claudication that failed progressed to rest pain with no tissue loss. This patient refused any further intervention. Similar to findings in the bypass vs angioplasty in severe ischemia of the leg (BASIL) trial,[11] four of the six failed SFA interventions had significant negative impact on patency of bypass grafts and limb salvage. It seems that the stenting first with no consequence adage can be detrimental to both limb salvage and to further attempts at revascularization.

We conclude that patients with advanced infrainguinal occlusive disease with CLI (TASC C/D lesions) would likely benefit from open surgical bypass over endovascular stenting. However, many of these patients are not appropriate surgical candidates and endovascular therapy is the only option. These patients present a difficult treatment dilemma for vascular surgeons. Based on our study, patients with CLI that undergo a failed percutaneous SFA intervention have a higher likelihood of amputation. Furthermore, stent thrombosis may have a negative impact on bypass patency. The higher amputation rates seen in patients with TASC C or D lesions compared to TASC A or B lesions again may just represent extension of disease. Randomized control trials comparing stenting vs open bypass in advanced TASC C and D lesions with limb salvage as the primary outcome would shed some light on the subject. Patients with advanced TASC C or D lesions that undergo stenting for claudication are more likely to fail than their TASC A or B counterparts, but a failed SFA intervention in these patients does not necessarily lead to amputation or bypass. Based on this experience, patients with lifestyle-limiting claudication with TASC C and D lesions that are appropriate surgical candidates and have adequate autogenous vein available should undergo open surgical bypass as opposed to endovascular therapy.

AUTHOR CONTRIBUTIONS

Conception and design: OA, BA, RM, PH, RH
Analysis and interpretation: OA, BA, RM, MK, RH
Data collection: OA, BA, RM, MK, AG, RH
Writing the article: OA, BA, RM, RH
Critical revision of the article: OA, BA, RM, RH, PH, AG
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DISCUSSION

Dr Peter Rossi (*Milwaukee, Wisc*). Thank you, Dr Al-Nouri, for the nice presentation. I would like to thank the program committee for giving me the opportunity to review this and thank Dr Al-Nouri for getting me the article several weeks ago. The article is a nice summary of isolated superficial femoral artery stenting for infrainguinal disease, and, despite the small number of patients in the series and the small number of limbs, I think it does give us some valuable insights. The 93% overall limb salvage rate in your article is laudable. It is interesting, though, that 31% of the cases that were done here were for TASC D lesions and 36% overall were done for claudication. When I examined the data and just sat down with a calculator, if I eliminated the claudication patients, the actual limb salvage rate for patients with chronic limb ischemia was down to 77%, and that's pretty comparable to previously published articles for redo infrainguinal bypass procedures. I'm a little bit curious. Could you comment on that? I have four overall questions regarding your manuscript. One, in your results in the manuscript, you mentioned that there were "500 lower extremity angioplasty and diagnostic angiogram procedures," so if I take it that you stented 42 of these, that gives you a 92% rate of isolated percutaneous transluminal angioplasty and you only stented about 8%. I'm wondering what your criteria were for actually placing stents and whether the fact that you stented a lesion meant that it was a higher-risk lesion and perhaps more likely to fail. Our group has previously shown that the number of patent runoff vessels is directly proportional to the rate of success of these procedures. You mentioned in your manuscript that you had an average of 2.1 patent tibial vessels in your procedures here, and I'm wondering if you examined the patency of the

runoff in terms of the success of the intervention. The third question is about your medical management. You did mention that the patients were on aspirin and Plavix, or one of the two. I'm curious as to whether you put these patients on statins or how involved you get in the medical management. There are certainly data that suggest improved patency and better outcomes with patients who are on statins and angiotensin-converting enzyme (ACE) inhibitors. I don't know if you're involved with that. Probably my only concern with the manuscript is that you do make the statement that the failure of these procedures for TASC C and D lesions leads to a decrease in limb salvage, and I'm not really sure that you showed that. The reason I say that is that they are moving on to having open revascularization, and at that point, your limb salvage rate is still very similar to previously published data for redo procedures. So I don't know if it's really that the failure of the procedure leads to a problem or if it just indicates more severe disease and they have to go on to another procedure, like they might traditionally have to. Thanks for allowing me to review this. I look forward to your responses.

Dr Omar Al-Nouri. Thank you, Dr Rossi. With regard to your first question, when you break it down, if you take away the claudication patients who were intervened on and you look at just the critical limb ischemia, the limb salvage is pretty comparable to open bypass. However, when SFA interventions fail, I think several recent studies have shown that it might not have an absolute effect on negative limb salvage, but it does change the distal target bypass, and that might decrease the patency of the open revascularization and make the bypass more difficult subsequently when you do have a failed SFA intervention, which could lead to decreased limb salvage. When we looked at the numbers for our patients, we used several CPT codes, and the 500 angioplasties that we looked at, those were not only just balloon angioplasty/stenting, but that included iliac interventions as well as diagnostic angiograms. So it was a large amount of data to go through to find just those 42 limbs. I think you're right, we specifically looked at patients that just underwent SFA stenting, we excluded patients that underwent only balloon angioplasty, thus, we're selecting out for these more advanced lesions and maybe setting it up for potentially having a failure. I'm sorry, the third and fourth questions? I apologize.

Dr Rossi. One was about medical management as far as using statins or ACE inhibitors, and the other was about the assumption that the failed percutaneous intervention leads to more difficult procedures for limb salvage.

Dr Al-Nouri. For the medical management, we have always put those patients on 30 days of Plavix postoperatively. We are pretty involved in the statin therapy with the medical doctors as well, so we do place the patients on statins if they were not on statins before and they have an indication to be on statin therapy. We talked about excellent vessel runoff, good vessel runoff, or poor vessel runoff, with a score of 3, 2, and 1, respectively, but did not break the patients down into these categories to see if they have a better patency rate the higher the runoff score is. We are still accruing data from the Veteran Affairs; once we have a more substantial number of patients, we will definitely look at patency rates broken down by runoff score.

Dr Karl Illig (*Rochester, NY*). I have good news and bad news for you. The good news is that your article was very well presented and your data were very clear, and I thank you very much for that. The bad news is that I have to pile on a little bit with regard to the prior discussant's fourth question. I don't think you have really answered what you have set out to ask. Rather, you've really sort of just reaffirmed the definitions of TASC C and D lesions. In other words, your results really are no more than the definitions of TASC C and D. The question you're trying to answer is if you initially approach a patient using endovascular techniques, do you burn your bridges; are you making things worse? A way of answering this would be to take your stented patients and blindly determine what a surgical bypass would have entailed, and then, when those who fail do so, compare what they end up requiring. If a patient would have required bypass to the popliteal level originally and then after a failed stent requires a pedal bypass, you've burned your bridges. Be careful about saying that just because some patients went on to amputation that you're doing anything good or bad – that is the natural history of this disease, and you cannot say that you have changed anything without some sort of control group.

Dr Al-Nouri. No, it's a very good question. We are also looking at our open bypass experience within the same time period. The idea when we set out looking at our SFA experience was how can we tie this in exactly with a failed SFA intervention? Does it burn our bridge in terms of the distal target that they might have? So it's one thing we are going to look at, as well as compare and look at the open bypass surgery and see, in this patient who failed and subsequently went on to have an open bypass, if it was the patency rate as opposed to someone who did not fail initially and see if those are comparable or not.

Dr Illig. Because your number is so small, for this article you could really very easily figure out what their bypass would have been and then what their bypass ended up being afterward.

Dr Al-Nouri. Yes.

Dr Philip Goodney (*Lebanon, NH*). That was nicely presented. I just wondered if you had calculated amputation-free survival curves or major adverse limb event curves. They would help to put into context some of the discussions that you've had with those who have come up to talk about your article. Patency is dependent upon how long a patient lives, of course, and you put a lot of stents into some very sick patients, and that might affect the overall limb salvage rate, just because a patient might not live long enough to get their amputation. Similarly, limb-specific outcome measures, such as the major adverse limb events, which is one of the Society for Vascular Surgery objective performance goals that we'll use to compare these results to open surgery, might effectively contribute to your study. I wonder if you have that information, and if you don't, will you put it in your manuscript?

Dr Al-Nouri. I don't have that information on hand right now. We're still looking at it. But we are looking at the amputation-free survival and it probably will be in the manuscript. You know, looking at amputation-free survival, that number might not be as significant as patency, and that's kind of why we wanted to specifically look at patency, because we did have a significant percentage of patients (36%) who were claudicants. Those patients should survive. So, amputation-free survival might not be the best indicator in patients with critical limb ischemia.

INVITED COMMENTARY

Ruth L. Bush, MD, MPH, *Temple, Tex*

The utilization of lower extremity endovascular interventions for the treatment of both claudication and critical limb ischemia has dramatically increased in the last decade. Part of this increase may be accounted for because of technological advances and part may be due to more aggressive treatment of patients considered high medical risk who would have previously been precluded from more traditional open bypass procedures. Dr Al-Nouri and colleagues have provided a detailed analysis of their institutional experience with endovascular interventions in the superficial femoral artery. Despite the small size of the study group and the cohort heterogeneity, their results have produced some important treatment options and essential patient messages that can be used by the peripheral interventionalist.